Texas Department of State Health Services
Radiation Safety Licensing Branch

REGULATORY GUIDE 3.10

GUIDE FOR THE PREPARATION OF LICENSE APPLICATIONS FOR VETERINARY BRACHYTHERAPY

I. Introduction

This guide describes the type of information that the Department of State Health Services (DSHS or Agency) staff needs to evaluate a license application for limited veterinary brachytherapy. For these purposes, brachytherapy is meant to include the use of sealed sources of radioactive material as temporary implants or surface applications treat animals, and would therefore include plesiotherapy (surface applications).

An application for use of radioactive material must be submitted in duplicate on the "Application for Radioactive Material License - Medical Uses" BRC Form 252-2a. BRC Form 252-2b, the Preceptor Statement, must be submitted in duplicate to document training for each veterinarian desiring to use radioactive material, if the [raining occurred within the last five years. In lieu of a Preceptor Statement, reference may be made to a Texas Radioactive Material License which names the veterinarian as an authorized user, or a copy of an out-of-state radioactive material license may be provided which shows such an authorization. The application forms with supporting documents should be mailed to the address specified at the top of BRC Form 252-2a. Applications for amendment to existing radioactive material licenses may be submitted on BRC Form 252-2a or by a letter stating the same information as specified on that form. The applicant should retain an additional copy of the application for his or her own files since once tile application has been approved he or she will be committed to operate under the procedures which have been submitted.

II. License Fees

An application fee is required for all specific licenses and must be submitted with any NEW application. The applicant should refer to Title 25 Texas Administrative Code (TAC) Section (§) 289.204 to determine the amount of fee that should accompany the application. Review Of the application will not begin until the proper fee is received by the Agency. The check or money order should be made payable to the Texas Department of State Health Services.

In the case of an application for renewal or amendment, a fee should NOT be submitted with the application. All current licensees will be billed according to the expiration month of their current license.

III. Instructions For Completing The Application

The separate items of the Application Form 41-2a are discussed below:

Item 1 - If a veterinarian is requesting use of radioactive material at his own office, then he or she is named as the applicant. If radioactive material is to be stored and used at an institution, the institution is named as the applicant. For cases where the treating veterinarian uses a private facility owned by others, the licensee could be the property owner, with the treating veterinarian named on the license as authorized user and Radiation Safety Officer. However, if the brachytherapy sources are received by the treating veterinarian at his or her own facility and subsequently transported to a separate site for therapeutic use, the first (receiving) facility would need to be licensed and so the separate therapy facility could be authorized as a subsite on the treating veterinarian's license with the separate therapy site owner's informed consent. The applicant and owners of the facilities involved should consider which method of licensure is most suitable for their respective business entities and long range plans. As special circumstances dictate, such as separate therapy site owners working in the employ of the treating veterinarian, additional descriptions of arrangements should be provided, and legal consultation may be desired. This guide covers only the brachytherapy use of radioactive material with temporary implants; it does not include diagnostic uses, use of therapeutic radiopharmaceuticals or other uncontained radioactive material, brachytherapy with permanent implants or teletherapy. Some of these uses are covered under a separate guides which are available from the Agency upon request.

Items 2 through 4 - Provide directions and descriptions of the site location(s) if street numbers are not available or are insufficient to describe or locate the sites of use. Also, if subsites are desired, confirm that copies of all records will be made available at the main site and provide consent of the property owners, as described above.

Item 5 - Provide the names, training and experience of each veterinarian to be named as an authorized user of radioactive material on the license, as indicated in I above. To use radioactive material in animals, an individual must be licensed in accordance with the laws of the State of Texas to dispense and use drugs in the prac-

tice of veterinary medicine, and have didactic and clinical radioisotope training and experience commensurate with the proposed use of radioactive material. Acceptable training and experience are specified in Appendix A of this guide. All brachytherapy procedures must be ordered and supervised by a suitably licensed and trained veterinarian.

Item 6 - The Radiation Safety Officer (RSO) is the person designated to be responsible for the day to day radiation safety program. He or she maintains all records required by the Agency rules. He or she also is the primary contact with the Agency on matters pertaining to the license and the use of radioactive materials. The RSO's training and experience with the types and quantities of radioactive materials for which authorization is sought should also be submitted.

Item 7 -

A. Group Uses - This does not apply to brachytherapy requests; leave blank.

B. Additional Items Desired -

Under (a) list isotope, i.e., "Iridium-192", "Gold-198" or "Sr-90", etc.
Under (b) give the sealed source manufacturer and model number for each model or type of source to be authorized.
Under (c) list maximum amount of material in millicuries to be possessed at any one time for each model or type of sealed source and give the nominal activity per source. Also provide a discussion of the maximum activity per treatment for each type or model of source: the license may need to reflect this as a fundamental restriction, depending on the radiation fields involved and the arrangement of physical facilities.
Under (d) for brachytherapy, list "interstitial treatment of cancer" if sources are for solid body tumor implantation or "treatment of superficial conditions', if applicators are requested. Sources should not be modified or used in a manner or under conditions that the manufacturer did not anticipate. Describe any special circumstances if this cannot be confirmed.

Item 8 and 9 -

A. Assume "veterinarian" in place of "physician". Also confirm that each individual has a license to practice veterinary medicine.

B. Certification of Using Veterinarians - Submit signed statements from each of the using veterinarians which certify that they are familiar with and agree to abide by the statement submitted with the application.

Item 10 -

A. Authorized Veterinarians - To use radioactive material in animals, an individual must be licensed in accordance with the laws of the state of Texas to dispense and use drugs in the practice of medicine, and have didactic and clinical radioisotope training and experience commensurate with the proposed use of radioactive material. Training and experience are specified in §289.256(ff)(1). If a veterinarian has been authorized within the past five years on another Texas radioactive materials license, evidence of this authorization may be submitted in lieu of training descriptions. This should include the license number, specific authorizations, and dates of practice.

B. Radiation Safety Officer (RSO) - The RSO is the person designated to be responsible for the day-to-day radiation safety program. The RSO maintains all records required by agency rules and is also the primary contact with the agency on matters pertaining to the license and the use of radioactive materials. The RSO's training and experience with the types and quantities of radioactive materials for which a license is being requested must be submitted. Qualifications may be found in §289.256(h), "Radiation Safety Officer."

C. Technicians and Attendants - If the radioactive materials are not to be used and handled exclusively by an authorized user or if animals are attended by individuals other than authorized users, describe the technician or attendant training, testing, and supervisory program as indicated below.

1. What minimum training must a technician or attendant have before he or she will be allowed to use or handle radioactive material or attend animals containing radioactive material? If training is not verified through a recognized certification program, describe the subjects and classroom hours of formal training to be given in basic radioisotope handling techniques, and the on-the-job experience, under close supervision, to be required.

2. How will performance be gauged in the training program? What written tests and on-the-job performance tests will be given to judge whether or not a trainee has satisfactorily completed the educational program? What periodic training, testing, and evaluation will be given thereafter?

Item 11 -

A. Facilities for temporary implant brachytherapy

Arrangements should be made for a surgical treatment (implant) area that is relatively isolated so that areas surrounding it that need to be restricted for radiation safety purposes to other properties or businesses. Following implantation of sources, the animal will need to be confined to a holding stall or pen for the duration of treatment and until the sources are removed. No exercising normally can be permitted because of the potential for source loss and attendant exposure and-so treatment durations should be compatible with this requirement. Describe

and fully justify any exceptions requested. The holding area or an adjacent area should also have provisions for retaining all excreta and segregation of any other material entering the holding stall, until final surveys and inventories can account for all of the sources used in therapy. An adjacent second stall for segregation of feed, excreta and treatment materials should be considered for large animals or when implant activity levels dictate mat entry into the treatment stall should be held to an absolute minimum. If more than one animal at a time will be undergoing therapy, the holding st,31. Is should be sufficiently separated so that the radiation field from one animal does not significantly contribute to the radiation exposure incurred while attending another, since this would unnecessarily increase attending personnel exposure.

The facility should be designed to assure containment of the small sources used in temporary implant brachytherapy. Floor drains in the surgery area should be sealed or finely screened during implantation and holding pens or stalls should be constructed so as to assure that any source that is dislodged by the animal's actions is confined to the stall. This may require the sealing of all openings greater than the source size, including doors and walls, to above the animal's height when standing. Sealing of wall sole plates, door sills, weather stripping of doors and jambs and provision of a liner (or equivalent) under a floor of bedding and/or soil, to minimize the volume of material to be searched for lost sources all should be considered or alternatives proposed. Hard surface stalls are not generally acceptable because of the possibility of source rupture, fragmentation and dispersion.

The animal should be easily visible during therapy to assess any distress and the condition of the treatment location on the animal, so adequate lighting and viewing windows should be provided, especially if the animal size requires containment walls to exceed five feet in height.

If the receiving and storage facilities are removed from the therapy facilities, provisions must also be made for safely receiving the sources, inventorying and temporarily storing them until needed, and as circumstances require, repackaging them for transport to the location of use.

The facilities which need to be described may thus include the site of use of the brachytherapy sources, the site of receipt and temporary storage for the sources when different, aha any transporting vehicle.

The fixed sites should be sketched to scale at several different scales to clearly show the following: details of rooms, stalls, and stanchions or other operatory fixtures, including construction details, where radioactive material will be used or stored; the location in the facility or the therapy rooms, stalls or stanchions, and uses of other areas of the facility including any residences; the proper~ as a whole, showing the facilities for treatment with respect other facilities, including residences, me property boundary, me access point to me property; me location

of the property and its surrounds, including the nearest neighboring residences or planned residences if known at the time of application.

Drawings should also indicate: the location of any shielding for radiation fields to be installed, should include a scale to allow distances between any two points to be accurately determined, should show which areas are to be restricted for radiation protection purposes, should show where security walls, doors and locks, fences and gates with locks are located to establish this restricted area or areas, and should also indicate which areas are designed for containment or the small sources to be used for brachytherapy, including sealable drains in the surgery area and liners, if needed, for the pens or stalls to be used for holding treated animals.

Accompanying descriptions should provide explanations of the drawings and any symbols used and include specifics on the following:

a. determination and enforcement of area restriction, use of surveillance, signs and locks for the areas where radioactive material is to be used.

b. source containment measures; liners for and gapless construction of pens and stalls up to a height of one to two feet above the treatment location for a standing animal.

c. animal visibility while in the stall (lighting,. windows, other) to examine the treatment site status or a distressed animal at anytime (without opening the stall or pen).

d. facility provisions for remote or rapid stall maintenance and feeding while occupied by an animal under treatment.

e. descriptions of the uses of adjacent areas of the facility and the property, keyed to locations on the drawing.

f. estimates of radiation fields at key locations (and certainly the restricted area boundaries) due to the maximum anticipated individual treatment activity and radiation doses per week or month at key locations clue to me average treatment activity, the average anticipated residence time in the location of surgery and in the holding pen or stall, and the minimum number of treatments expected (or to be authorized) per week or month. Indicate the values and the expected ranges of each of these parameters that contribute to the dose estimates.

Brief drawings and descriptions should be provided for the source receipt and temporary storage facility if different from the therapy facility.

Any vehicle used for transport of sources from a receiving site to the therapy facility should be described, particularly with respect to where and how the sources will be secured for transport, the minimum distance from the sources to each vehicle occupant (provide a diagram also), and the maximum radiation field and exposure time for each occupied position in the vehicle. The assessment should include a realistic travel time estimate from the source receiving and storage site to the site of use.

Item 12 - Radiation Safety Procedures - The applicant's Radiation Safety Procedures must be submitted in duplicate with numbered pages and a table of contents and should include the following items as appropriate for the uses desired.

1. A description of the duties of the Radiation Safety Officer (RSO) and the program for periodically checking on the use of radioactive material and reviewing records to assure that proper safety procedures are followed. The RSO must have authority to set radiation safety policy for all sites of use, to stop any use of radioactive material deemed unsafe and to require remedial action by users.

2. If, after implant, the RSO or treating veterinarian is not at or immediately available (within thirty minutes) to the treatment facility, arrangements should be made with a local radiation safety expert, who can be immediately available, to advise and assist attending personnel 6n radiation safety matters regarding brachytherapy in the activity ranges to be authorized.

   Confirm that, prior to any treatment, either the treating veterinarian (or RSO) or the local radiation safety expert, or both, will be given the authority by the animal owner, property owner and/or licensee, as required, to exercise his or her judgment with regard to human radiation safety and hazards during the course of treatment, without, if necessary, regard for the consequences to the animal under treatment. Additional administrative procedures should be provided also (see Appendix C for content of these procedures).

3. The method of ordering and receiving radioactive material, promptly notifying responsible persons, monitoring it for contamination and radiation fields, and storing it securely. Receipt of material after normal working hours should be specifically addressed.

4. The method of recording receipt, authorized use, transfer, inventory, and disposal of radioactive material. This should include records to indicate that only authorized users are ordering and supervising the therapy procedures. Also describe where records are to be kept for each phase of the operations. Copies of all records must be maintained at the main site for Agency review, if more than one site is involved.

5. The method of restricting access to radioactive material to authorized users. Also, the method of controlling access to restricted areas, radiation arms, and high radiation areas.

6. Describe the source handling and implanting procedures for the brachytherapy sources in a step by step manner, including sterilization, use of shielded containers and long or remote handling tools, portable or fixed shielding, loading of applicators or cartridges, implantation or after-loading, physical security provisions of sources while implanted, recovery of sources from treatment sites on or in the animal and any cleaning needed, reshiefding of unused sources, and any source position verification procedures performed after implant that would expose individuals to the brachytherapy fields (such as x-ray localization, etc.). Describe also who will perform each of these steps and who will be present in the operatory when the sources are present.

7. Describe the frequency and method that will be used to test the brachytherapy sources for leakage if the sources are to be retained longer than six months. For example, if a commercial kit is used, name the supplier.

   If the applicant wishes to test his or her own sources for leakage, the procedures for wiping, counting, converting to microcuries, etc. must be submitted. (Regulatory Guide 5.1, "Guide for the Preparation of Leak Test Applications," may be obtained from the Agency.)

8. Provide procedures for preparing and packaging a shipment of sources to the treatment facility, if separate from the storage facility. Describe the surveys, package types and construction and labels to be used. Which will be in accordance with U.S. Department of Transportation (DOT) regulations. What records will be made and manifests be prepared? How will the sources be logged out of inventory and back in upon their return?

9. Describe transportation procedures to include instructions on location and physical arrangement of the source containers, the manifest to be carried, written emergency instructions for the driver in case of vehicular accident (and printed summary instructions for emergency workers in case the driver is incapacitated). Describe who will transport the sources, their training and experience with radioactive material (if they are not listed on the license as authorized users), and prohibitions against non-business use of the vehicle and non-essential vehicle occupants during source transport. Confirm after each one-way transport trip, the vehicle will be surveyed to verify that all sources have been removed. Confirm also a current copy of the radioactive material license will be carried in the vehicle, a working and calibrated survey meter will be present, and, if the driver and/or occupants are not listed on the license, written and dated authorization (from an authorized user) will be carried for each of the vehicle's occupants who are to be in the vehicle while the sources are being transported.

10. Describe radiation surveys to be made routinely and surveys for radiation fields and contamination control that may be necessary if a source is broken or crushed. Routine surveys should be made of implant operatories and holding areas, after the animal and any other sources have been removed, to verify that no sources have bee lost or displaced, regardless of inventory results. Also, to assist in source surveillance during the treatment period, surveys at a standard distance (2 meters for example) from the treatment site on the animal should be made immediately after implant, and this value compared to subsequent surveys during the treatment period to verify that the sources are still in place.
    Such surveys should be made from outside the occupied holding stall, if at all possible. These surveys should also be used to provide for area restriction around the treated animal's holding stall as indicated in 14 below.

11. Indicate the method of monitoring personnel exposure (film badges, TLD, etc.) and the personnel monitor supplier. NOTE: 25 TAC §289.202(g) details supplier accreditation requirements. If millicurie amounts of activity are used at one time, confirm that ring badges will be used by persons handling those amounts of activity. If large activities .are to be used per treatment (greater than 500 mCi), describe an immediate readout dosimetry program as a supplement to standard methods (pocket chambers, self-reading dosimeters, etc.)

12. Describe general laboratory rules for preventing unnecessary radiation exposure when handling or working around the brachytherapy sources (see Appendix D) and for preventing loss of the sources during implantation or therapy.

13. Describe the instructions to individuals attending animals containing radioactive sources. The instructions should assure proper protection of other individuals of the facility and visitors as well. Include times and distances from the animal which should be observed for routine care, the types of emergencies which can safely be handled by attendants, and the situations that should be referred to an authorized user, the RSO or a local radiation safety expert (see 15 below).

14. Explain procedures for performing radiation surveys about animals containing brachytherapy sources and for restricting the area about each animal. Also, provide procedures for surveying animals and holding stalls to verify that all temporary implants have been removed prior to the animal's release from the facility. Confirm that, if the animal under treatment expires, the sources will be removed and confirming surveys made, as above.

15. Provide summary emergency instructions to be posted and followed for the most likely emergencies; for more serious problems these should indicate what should be done during the time period before a radiation safety expert arrives on site.

16. Describe in detail what should be done if a source is lost in the surgery area, the holding area and/or if the location of source loss is unknown. What will be done if a source holder or career is damaged or broken in handling or in the implanting

process. What will be done if a source is damaged (cut, broken or crushed). Depending on facility design and procedures, source recovery or contamination clean up could require extensive work (removal and replacement of sewer lines, septic tanks, disposal of large amounts of material). Describe financial resources and owner awareness (if not addressed in Item 2) for such a potential liability.

17. A description of the method for managing and disposing of radioactive wastes, such as unused, unwanted or decayed sources. What will be done with clean up material if a source is damaged and contaminated materials are produced?

18. State how often and by whom the survey instruments will be calibrated and describe how corrections are made for the energy of the isotopes being used. (Regulatory Guide 5.2, "Guide for the Preparation of Survey Instrument Calibration Applications," may be obtained from the Agency if survey instrument calibration is to be done by the licensee.)

19. How will a technician or attendant be supervised on-the-job? How frequently will his or her performance be observed by a licensed user to verity mat established procedures are being followed? How will the licensed user verify that established procedures will be followed in his absence (review of records, observation by others)? Describe the normal availability of the licensed user or the local radiation safety expert (see 10B.2.) to the technician or attendant (time and distance away) during routine operations, should a problem arise.

Item 13 - Radiation Detection Instrumentation - Describe type and ranges of survey instruments. Ranges should extend to I R/hour for at least one instrument.

Item 14 - See 25 TAC §289.252(gg) to determine if financial assurance must be provided. Unless licensed authorizations include large amounts of long-lived radioactive material (i.e., half-lives greater than 120 days), financial assurance is not required and financial qualification can be established by self-attestation on BRC Form 252-1, Business Information Form.

Item 15 - The application must be signed and dated by the applicant or an individual duly authorized by the applicant to act for or on the applicant's behalf. Unsigned and undated applications will be returned to the applicant. Retain one copy for your files and mail the license applications and appropriate fee to:

Texas Department of State Health Services
Radiation Safety Licensing Branch
Medical and Academic Licensing Program
1100 West 49th Street
Austin, Texas 78756-3189

Appendix A

ACCEPTABLE TRAINING AND EXPERIENCE FOR VETERINARY BRACHYTHERAPY USES OF RADIOACTIVE MATERIALS

I. Training For Veterinary Brachytherapy Licensing

To qualify as adequately trained to use or directly supervise the use of radioactive material for veterinary brachytherapy, a veterinarian should have:

A. Training in basic radioisotope handling techniques consisting of lectures, laboratory sessions, discussion groups or supervised experience in a nuclear medicine laboratory in the following areas: (200 hrs)

1. Radiation physics and instruments (100 hrs)
2. Radiation protection (30 hrs)
3. Mathematics pertaining to the use and measurement of radioactivity (20 hrs)
4. Radiation biology (20 hrs)
5. Sealed source handling techniques (30 hrs)

(The hours listed next to each of the five subjects above are suggested values and should no/be interpreted as specific requirements.)

B. Experience with types and quantities of radioactive materials for which the application is being made, or equivalent (500 hrs).

C. Supervised clinical training in an institutional veterinary nuclear medicine program (500 hours), preferably at a teaching hospital or in a university veterinary medicine program. The clinical training should cover all appropriate types of therapeutic procedures and include:

1. Supervised examination of animals to determine the suitability of radioisotope therapy and recommendations on dosage to be prescribed.

2. Collaboration in calibration of the dose and the actual administration of the dose to the animal, including calculation of the radiation dose, related measurements, and plotting data.

3. Follow-up of treated animals when required.

4. Study and discussion with preceptor of case histories to establish most appropriate therapeutic procedures, limitations, contraindications, etc.

NOTE: The requirements specified in Sections A, B, and C may be satisfied concurrently in a three-month training program if all three areas are integrated in-

to the program. Also, if training occurred more than five years prior to application for use, evidence of licensed practice in the field or additional current training will be needed.

Alternative to B and C

- active practice in therapeutic radiology with a minimum of three years experience.

Alternative to A, B, and C

- specialty board certification and active practice in therapeutic radiology may satisfy Agency requirements if the specialty board certification requires training equivalent to that in Sections A, B and C above. The applicant should provide details of the specialty board's requirements and evidence of active practice in the interium, if certification was more than five years prior to application.

Appendix B

METHODS AND FREQUENCY FOR CONDUCTING
RADIATION SURVEYS

I. Introduction

When radioactive material is handled in the form of sealed sources, surveys for radiation fields assist most in reducing hazards for the individuals involved and a schedule of routine surveys should be established. Contamination surveys may also need to he performed on occasion, to prevent the spread of contamination throughout a facility if damage to the sealed sources is suspected or demonstrated. Periodic contamination tests of instruments used to directly handle the sources should provide sufficient warning of such damage without undue personnel exposure. Radiation field surveys are performed using an appropriate radiation survey meter, and contamination surveys are performed by taking wipe samples from surfaces in the facility that are likely to be contaminated and counting the samples with a suitable detector.

II. Frequency of Surveys

The frequency of surveys for veterinary brachytherapy depends, upon the amount, and type, of radioactive material used. Listed below are examples that may be useful in determining how often to perform surveys. The greater the workload, the more often the surveys should be performed.

A. Low Level Areas - Sources less than 100 uCi each. Brachytherapy uses will not usually have such small sources and thus areas will not qualify for such infrequent surveys.

B. Medium Level Areas - Not less than once a week - Areas where therapeutic sources are stored between uses.

C. High Level Areas - Not less than once a day - Areas used for packaging, transport, preparation or use of therapeutic sources.

III. Methods of Surveys

Suggested methods for performing the two types of surveys are given below. Records of these surveys are required for inspection by the Agency and should be chronologically maintained for reference.

A. Radiation Area Survevs - A survey meter capable of measuring levels as low as 0.1 mR/h should be used to measure radiation fields in occupiable areas near sources which are stored or in use. The results should be recorded on a standard form showing location, date, person performing survey, instrument used, expo-

sure levels, and corrective action taken, if any. The boundaries of the restricted areas should be measured to confirm that they are properly located and the sources are properly stored or shielded. A sketch of the area should be used to make an easily prepared and understood survey record when annotated with this information.

B. Contamination Surveys - A series of wipes using filter papers, swatches of cloth or other should be taken from those surfaces where contamination could be expected to show up first from damaged sources. Likely areas include source containers and shields, handling tools and devices, sterilizing equipment, operatory surfaces and any areas where lost or misplaced sources are recovered, including walkways and holding areas. The wipes should be numbered or labeled and the location where they are taken shown on the sketch as described above for the radiation surveys. The wipes should each be rubbed over the amount of removable contamination. The wipes may be counted using a gamma scintillation well counter, a geiger counter, or other detector capable of detecting the small amount and type of contamination on the sample which is of interest (see IV. below). The amount of removable activity should be recorded in activity units (dpm, bequerels, or microcuries) per unit area if above acceptable limits. Calculations for converting instrument readings to activities is usually required and should be explained. If the reading is less than acceptable limits, the instrument reading may be recorded.

IV. Acceptable Limits

A. Radiation Levels - In areas that are unrestricted (uncontrolled) no radiation levels should exist such that a person could receive 500 mR in any one year, 100 mR in any seven consecutive days, or 2 mR in any one hour. If such areas are found to exist, measures should be taken to eliminate the excessive radiation levels. Additional shielding or relocation of radioactive material may be required.

In restricted areas, the exposure limits do not apply since personnel are monitored to determine their exposure. However, levels should be reduced to the minimum where practicable to keep exposures as low as reasonably achievable. Visitors would not be allowed in restricted areas.

B. Contamination Limits - If the wipe samples of an approximately 100 square-centimeter area indicate more than 1,000 disintegrations per minute (dpm), the area should be cleaned until the contamination has been reduced to background activity. Since it is difficult to determine exactly when a wipe sample has 1,000 dpm, it is recommended that, if such samples show an easily detectable amount of activity above background, the areas from whence they came be cleaned to remove all radioactive contamination. This action should help prevent the spread of contamination and ingestion of activity by personnel whose hands or clothing have become contaminated. Any contamination detected should also be brought to the attention of the RSO and/or the Agency when required, since such con-

tamination implies that a source has been damaged. All operations should be curtailed as quickly. as possible until the cause and extent of the source damage is determined and the remaining sources leak tested. Sources found leaking or damaged should be immediately withdrawn from service and stored safely until they can be disposed of by appropriate means.

Appendix C

ADMINISTRATIVE PROCEDURES

If, after implant, the RSO or treating veterinarian will not normally be present when radioactive material is in use in animals, additional administrative procedures for controlling and supervising the radiation safety program should be submitted. The procedures should include at least the following:

1. The procedures to be followed in notifying the RSO or treating veterinarian (or local radiation safety alert if travel times for the others would exceed 30 minutes) when his or her presence is needed to assist with radiation safety or resolve a problem.

2. If the RSO or treating veterinarian is not located within 30 minutes travel time of the treatment facility and a local radiation safety expert is appointed, describe the training and experience in radiation safety which would qualify him/her to oversee veterinary brachytherapy and describe his/her location and availability during therapy with respect to the treatment location. Will he/she be notified prior to a therapy case and agree to be available on short notice (30 minutes or less), should a significant safety problem arise?

3. The names of the individuals who will be at the facility to attend the animals under treatment with radioactive material when the RSO, treating veterinarian or local radiation safety expert is not present. Describe their training and experience with radiation safety.

4. What instruction will be provided to animal attendants to assist them in determining when the RSO, treating veterinarian or local radiation safety expert should be contacted for assistance in resolving a problem?

5. Indicate how often the RSO will observe the operations of the animal attendants to ensure that the approved radiation safety procedures are being followed.

6. How will the RSO assure that the radiation safety procedures are being followed when he or she is not present at the facility?

7. A description of the records to be kept at the facility where the radioactive material is actually used. Records should include the specifics of each therapeutic use, surveys, and personnel monitoring. Note that copies of these records should also be available at the main site if the treatment location is at a secondary location.

Appendix D

GENERAL GUIDELINE FOR SAFE USE OF RADIOACTIVE MATERIAL
IN VETERINARY BRACHYTHERAPY

The following is an example of typical safety rules that could be specified for a facility using or preparing radioactive material for veterinary, brachytherapy. The applicant is encouraged to develop his/her own set of such rules that are specific to his/her needs and actual laboratory situation. Rules should be written in the form of directives to be followed by employees and that format is used in this example, for illustration.

1. Wear personnel monitoring devices (film badges or TLDs) at all times while in areas Where radioactive materials are used or stored. One device shall be worn at chest or waist level. Personnel monitoring devices, when not being worn to monitor occupational exposures, shall be stored in a designated low background area, as shall the control badge.

2. Always were extremity monitors if you will be handling the sealed sources used in brachytherapy, device used with the sources, assisting in the implantation or closely attending the animals during the therapy period.

3. Use time and distance to keep your exposure to radiation fields at a minimum. Plan operations in such a way that they can be performed quickly and efficiently, and at as much distance from sources of radiation as is consistent with efficiency. Observe any restrictions in time or distance indicated by the veterinarian's written orders for each animal.

4. Be knowledgeable of radiation field locations and intensities by performing radiation field surveys with a calibrated survey meter. When duties do not require entry into these areas, they are to be avoided.

5. Confine radioactive sources which are not in use to shielded containers that are clearly identified and labeled with the name of the sources, isotope, date, activity and radiation levels, as applicable.

6. Always transport radioactive material in shielded, labeled containers.

7. Make sure areas where implants are to be done are configured to prevent loss of sources and easy recovery if sources are dropped or misplaced. Work surfaces are to have raised edges to facilitate containment, drains must be blocked or have fine screens; all operating materials and fluids will be held in special containers until all sources are accounted for after implant or until the materials are surveyed with a sensitive survey meter to verify the absence of misplaced sources.

8. Work with sources must occur only in the designated areas. Temporary storage, cleaning and other ancillary operations must also be confined to the authorized areas.

9. Survey the operatory, the holding areas and all animal waste after each procedure to verify the absence of lost sources.

10. Conduct careful source inventories before implantation and after source recovery from the treatment sites. Notify the appropriate individuals and initiate operations to recover any sources that are not accounted for.